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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,911	07/03/2003	Philip E. Wolfson	19641.06	5582

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LITMAN LAW OFFICES, LTD  
PO BOX 15035  
CRYSTAL CITY STATION  
ARLINGTON, VA 22215

EXAMINER

MCCORMICK EWOLDT, SUSAN BETH

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/611,911

Applicant(s)

WOLFSON, PHILIP E.

Examiner

S. B. McCormick-Ewoldt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-15 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

The amendment of July 5, 2005 is hereby acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Status of Application**

The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1655.

**Election/Restrictions**

Applicant's election with traverse of species elected, *Nicotiana glauca*, in the reply filed on July 5, 2005 is acknowledged. The traversal is on the ground(s) that a search and examination of the entire application could be accomplished without serious burden on the Examiner since the multiple species would seemingly encompass a common field of search. This is not found persuasive because each species would have to be searched individually which would be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

**Claims Pending**

Applicant has cancelled claim 1 and has previously added claims 2-15 dated April 4, 2005. Newly submitted claims 13-15 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 13-15 are directed towards a method.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In claim 4 the recitation “ a trace amount” does not have clear metes and bounds. Clarification is needed.

Applicant’s arguments filed July 5, 2005 have been fully considered but they are not persuasive. Applicant argues that the terminology “a trace amount” clearly sets forth that the composition may be formulated to contain “quantities substantially less than the naturally occurring nicotine agonist alkaloids” in the specification. This is not persuasive as the term “trace” is defined as “a very small amount” and “a constituent, element or chemical compound present in less than standard quantities.” This recitation is not clear what is encompassed by “trace amount.”

Claim Rejections - 35 USC § 102

Claims 2-13 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wolfson *et al.* (US 6,534,527) as stated in the previous Office action. Applicant’s arguments filed April 4, 2005 and July 5, 2005 have been fully considered but they are not persuasive.

Wolfson *et al.* (US 6,534,527) expressly teach using *Nicotiana glauca*, which contains the alkaloids anabasine and anatabine, in a composition for abstaining or reducing nicotine intake wherein *Nicotiana glauca* has a nicotine percentage of 0% weight to trace amount and the anabasine amount is at least 0.2 % by weight of the herbal component (column 2, lines 6-20, 28-30). Wolfson *et al.* also teach dosage amounts of the herbal component from about 200 mg to about 600 mg (dry weight) and 50 mg to about 400 mg liquid extract of the herbal component (column 3, lines 44-49). The anabasine content per dose is in the range of 0.2 mg to about 10 mg (column 3, lines 33-35). In addition, Wolfson *et al.* also teaches the carrier is formulated into

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dosage units such as tablets, lozenges, chewing gum and a liquid preparation with local effects on the mouth and throat, all which have sublingual and mucosal effects (column 4, lines 38-45).

**Applicant argues** that Wolfson *et al.* teaches using multiple nicotine agonists one of which is anabasine in an amount of at least 0.2 weight percent. This is not persuasive as Wolfson *et al.* teaches using “about 0.2 weight percent”. The term “about” is defined as “reasonably close to.” In addition, claim 2 specifies that the anabasine is “at least” 0.1 percent. “At least” encompasses the amounts specifically taught by Wolfson.

**Applicant argues** that Wolfson *et al.* does not teach the absorption of the nicotine agonist through mucosal lining of the oral cavity and into circulation. This is not persuasive as Wolfson *et al.* teaches the component in a tablet, capsule, lozenge or liquid preparation for oral administration with local effects in the mouth and throat (column 4, lines 38-45). The term mucosal relate to the membranous tissue of an oral cavity. The term sublingual is defined as “situated beneath or on the underside of the tongue.” The administration of lozenges or liquid preparations would satisfy this requirement.

Therefore, the rejection is proper and is maintained.

#### Summary

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

*Susan D. Coe*  
8-29-05  
**SUSAN COE**  
**PRIMARY EXAMINER**